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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,913	01/25/2002	Harish C. Joshi	E2690/268902	3014

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EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

#8

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,913

Applicant(s)

JOSHI ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Status of Claims

1. Claims 1-22 are pending.
2. Claims 1-22 are rejected.

Response to Arguments

3. Applicants' arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

4. The information disclosure statement filed on July 30, 2002 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

Claim Rejections - 35 USC § 112

5. The rejection of claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of tumors, does not reasonably provide enablement for the prevention of tumors is withdrawn in response to the amendment of October 23, 2002.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. The following explanation supports this rejection.

Independent claims 1 and 19 state that the variable of D can be represented by the group " -CH(O)-" However, the valency of the carbon atom is exceeded in for this group. As a result, these claims are rendered vague and indefinite.

8. The rejection of claims 19-22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically regarding the anomaly with listing of component (a) is withdrawn in view of the amendment of October 23, 2002.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ye et al. in view of the following four articles entitled, "Offering Hope in the Treatment of

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Brain Cancer," [online], [retrieved on 2002-01-16], retrieved from the Internet

<URL:<http://www.gliadel.com> >; the article entitled "A General Description", [online],

[retrieved on 2002-01-16], retrieved from the Internet <URL:

<http://www.alzet.com/products/products-sec01.html> >; the website article entitled,

"Duros", [online], [retrieved on 2002-01-22], retrieved from the Internet <URL:

<http://www.durect.com/wt/durect/page-name/duros>>; and the article entitled, "The Brain

Infusion Kit and Brain Infusion Kit II", [online], [retrieved on 2002-01-16], retrieved from

the Internet <URL: <http://www.alzet.com/products/products-sec05.html>>. Ye et al.

disclose of the administration of the alkaloid, noscapine, as an antitumor agent, (see

pages 1601 and 1606). The website article entitled, "Offering Hope in the Treatment of

Brain Cancer," [online], [retrieved on 2002-01-16], retrieved from the Internet

<URL:<http://www.gliadel.com> > teaches of the mode of administering a pharmaceutical

as a wafer, (see article). Next, the website article entitled, "A General Description",

[online], [retrieved on 2002-01-16], retrieved from the Internet <URL:

<http://www.alzet.com/products/products-sec01.html> > discloses of osmotic pumps for

the administration of pharmaceuticals, (see article). The website article entitled,

"Duros", [online], [retrieved on 2002-01-22], retrieved from the Internet <URL:

<http://www.durect.com/wt/durect/page-name/duros>> provides the skilled artisan with the

motivation to employ implant technology for the administration of pharmaceuticals to an

individual, (see article). In addition, the website article entitled, "The Brain Infusion Kit

and Brain Infusion Kit II", [online], [retrieved on 2002-01-16], retrieved from the Internet

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<URL: <http://www.alzet.com/products/products-sec05.html>> discloses of the administration of pharmaceutically active agents brain infusion kits, (see article).

The instant invention recites various modes and methods for pharmaceutical administration, such as implantable devices, delivery pumps, wafers. It is well within the purview of the skilled artisan to determine dosages, modes and methods of administration. In addition, the one having ordinary skill in the art would be motivated to determine optimum amounts as well as modes and methods of administration in order to get the maximum effect of the pharmaceutical agent. Accordingly, these references make obvious the instant invention.

12. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ke et al. in view of the following four articles entitled, "Offering Hope in the Treatment of Brain Cancer," [online], [retrieved on 2002-01-16], retrieved from the Internet

<URL:<http://www.gliadel.com> >; the article entitled "A General Description", [online], [retrieved on 2002-01-16], retrieved from the Internet <URL:

<http://www.alzet.com/products/products-sec01.html> >; the website article entitled,

"Duros", [online], [retrieved on 2002-01-22], retrieved from the Internet <URL:

<http://www.durect.com/wt/durect/page-name/duros>>; and the article entitled, "The Brain Infusion Kit and Brain Infusion Kit II", [online], [retrieved on 2002-01-16], retrieved from the Internet <URL: <http://www.alzet.com/products/products-sec05.html>>. Ke et al.

disclose that the alkaloid of noscapine is effective in the inhibition of tumor growth, (see abstract and pages 223-224). The website article entitled, "Offering Hope in the Treatment of Brain Cancer," [online], [retrieved on 2002-01-16], retrieved from the

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Internet <URL: <http://www.gliadel.com> > teaches of the mode of administering a pharmaceutical as a wafer, (see article). Next, the website article entitled, "A General Description", [online], [retrieved on 2002-01-16], retrieved from the Internet <URL: <http://www.alzet.com/products/products-sec01.html> > discloses of osmotic pumps for the administration of pharmaceuticals, (see article). The website article entitled, "Duros", [online], [retrieved on 2002-01-22], retrieved from the Internet <URL: <http://www.durect.com/wt/durect/page-name/duros> > provides the skilled artisan with the motivation to employ implant technology for the administration of pharmaceuticals to an individual, (see article). In addition, the website article entitled, "The Brain Infusion Kit and Brain Infusion Kit II", [online], [retrieved on 2002-01-16], retrieved from the Internet <URL: <http://www.alzet.com/products/products-sec05.html> > discloses of the administration of pharmaceutically active agents brain infusion kits, (see article). The instant invention recites various modes and methods for pharmaceutical administration, such as implantable devices, delivery pumps, wafers. It is well within the purview of the skilled artisan to determine dosages, modes and methods of administration. In addition, the one having ordinary skill in the art would be motivated to determine optimum amounts as well as modes and methods of administration in order to get the maximum effect of the pharmaceutical agent. For these reasons, these references make the instant application obvious to one having ordinary skill in the art.

13. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ye et al. in view of Windholz, M. et al., Editor, The Merk Index, 10th Edition. Ye et al. disclose of the administration of the alkaloid, noscapine, as an antitumor agent, (see

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pages 1601 and 1606). Windholz et al. teach of various and sundry antineoplastic and antitumor agents, such as cyclophosphamide, cisplatin, vinblastine, vincristine and vindensine, (see pages 394, 329, 1427, 1428, 1428 and 1428-1429, respectively).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). For these reasons, it would have been obvious to one having ordinary skill in the art to modify the prior art teachings by combining these pharmaceuticals, especially when they possess the same utility as antineoplastic agents.

14. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ke et al. in view of Windholz, M. et al., Editor, The Merk Index, 10th Edition. Ke et al. disclose of the administration of the anti-microtubule agent of noscapine as an effective chemotherapeutic agent for the treatment of human cancer, (see pages 217 and 223 and 224). Windholz et al. teach of various and sundry antineoplastic and antitumor agents, such as cyclophosphamide, cisplatin, vinblastine, vincristine and vindensine, (see pages 394, 329, 1427, 1428, 1428 and 1428-1429, respectively). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ

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1069, 1072 (CCPA 1980). Thus, the skilled artisan would have been motivated to combine the prior teachings of Ke et al. in view of Windholz, M. et al. in order to generation a new composition which is used for the very same utility.

15. The rejection of claims 1-18 under 35 U.S.C. 103(a) as being unpatentable over Al-Yahya et al. in view of Hyon et al. of U.S. Patent No. 5,100,669 is removed in response to the amendment of October 23, 2002.

16. The rejection of claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Yahya et al. in view of Bar-Shalom et al. of U.S. Patent No. 5,213,808 is removed in response to the amendment of October 23, 2002.

17. The rejection of claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sam et al. in view of Hyon et al. of U.S. Patent No. 5,100,669 is removed in response to the amendment of October 23, 2002.

18. The rejection of claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sam et al. in view of Bar-Shalom et al. of U.S. Patent No. 5,213,808 is removed in response to the amendment of October 23, 2002.

Obviousness-type Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,376,516 in view of the following four articles entitled, "Offering Hope in the Treatment of Brain Cancer," [online], [retrieved on 2002-01-16], retrieved from the Internet <URL:<http://www.gliadel.com> >; the article entitled "A General Description", [online], [retrieved on 2002-01-16], retrieved from the Internet <URL: <http://www.alzet.com/products/products-sec01.html> >; the website article entitled, "Duros", [online], [retrieved on 2002-01-22], retrieved from the Internet <URL: <http://www.durect.com/wt/durect/page-name/duros>>; and the article entitled, "The Brain Infusion Kit and Brain Infusion Kit II", [online], [retrieved on 2002-01-16], retrieved from the Internet <URL: <http://www.alzet.com/products/products-sec05.html>>. U.S. Patent No. 6,376,516 discloses of the administration of the noscapine compounds of formula (I) as an effective chemotherapeutic agent for the treatment of human cancer and tumor cells. The website article entitled, "Offering Hope in the Treatment of Brain Cancer," [online], [retrieved on 2002-01-16], retrieved from the Internet <URL:<http://www.gliadel.com> > teaches of the mode of administering a pharmaceutical as a wafer, (see article). Next, the website article entitled, "A General Description", [online], [retrieved on 2002-01-16], retrieved from the Internet <URL: <http://www.alzet.com/products/products-sec01.html> > discloses of osmotic pumps for

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the administration of pharmaceuticals, (see article). The website article entitled, "Duros", [online], [retrieved on 2002-01-22], retrieved from the Internet <URL: <http://www.durect.com/wt/durect/page-name/duros>> provides the skilled artisan with the motivation to employ implant technology for the administration of pharmaceuticals to an individual, (see article). In addition, the website article entitled, "The Brain Infusion Kit and Brain Infusion Kit II", [online], [retrieved on 2002-01-16], retrieved from the Internet <URL: <http://www.alzet.com/products/products-sec05.html>> discloses of the administration of pharmaceutically active agents brain infusion kits, (see article). The instant invention recites various modes and methods for pharmaceutical administration, such as implantable devices, delivery pumps, wafers. It is well within the purview of the skilled artisan to determine dosages, modes and methods of administration. In addition, the one having ordinary skill in the art would be motivated to determine optimum amounts as well as modes and methods of administration in order to get the maximum effect of the pharmaceutical agent. For these reasons, these references make the instant application obvious to one having ordinary skill in the art.

21. Claims 19-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,376,516 in view of Windholz, M. et al., Editor, The Merk Index, 10th Edition. U.S. Patent No. 6,376,516 discloses of the administration of the noscapine compounds of formula (I) as an effective chemotherapeutic agent for the treatment of human cancer and tumor cells. Windholz et al. teach of various and sundry antineoplastic and antitumor agents, such as cyclophosphamide, cisplatin, vinblastine, vincristine and

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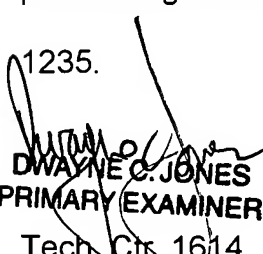
vindensine, (see pages 394, 329, 1427, 1428, 1428 and 1428-1429, respectively). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Thus, the skilled artisan would have been motivated to combine the prior teachings of U.S. Patent No. 6,376,516 in view of Windholz, M. et al. in order to generation a new composition which is used for the very same utility.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
January 7, 2003